REMARKS

I. STATUS OF THE CLAIMS

By this Amendment, claims 9-16 have been newly added. Thus, claims 5-16 are currently pending. Support can be found throughout the specification and claims as originally filed. For example, support can be found in the specification at page 1, lines 9-13, and pages 22-27. No new matter has been added.

II. INTERVIEW SUMMARY

Applicant thanks the Examiner for her time conducting a telephonic interview with their undersigned representative on September 8, 2004. The rejections under Section 112 were discussed during the interview. The Examiner explained that the statement "[t]he Court holds..." on page 2, section 3 of the Office Action is based on *Splendor Form Brassiere, Inc. v. Rapid-American Corp.*, 187 USPQ 151 (SD NY 1975). The Examiner also indicated that the rejection of the present claims as lacking written description and enabling support for allegedly being directed to a "mechanism ... without any end result..." (Office Action, pg. 3) is based on a policy of the U.S. Patent and Trademark Office to reject so-called "mechanism" claims. To the extent the Examiner's position has been properly understood, Applicant hereby requests a written copy or formal explanation of any such policy concerning "mechanism" claims.

III. REJECTIONS UNDER 35 U.S.C. § 112

Claims 5-8 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly (a) failing to comply with the written description requirement and (b) lacking an enabling

description. (Office Action, pg. 2-3.) Applicant respectfully disagrees, and traverses the rejections for at least the following reasons.

As a preliminary matter, Applicant disagrees with the Office's characterization of the claims as directed only to a mechanism of treatment. (*See, e.g.,* Office Action, pg. 3 ("The instant claims [are] directed to a mechanism of inhibiting urease activity or Helicobacter pylori activity without the end results would therefore have no practical utility....").) For example, in contrast to this characterization, claim 5 is directed at inhibiting a specific enzyme (urease), the product of which (urea) is known to cause, for example, gastrointestinal problems. Similarly, claim 8 is directed to inhibiting Helicobacter pylori, a known infection that can cause adverse effects. Although specific diseases, such as ulcers, that may result from urease or Helicobacter pylori are not mentioned in the claims it is improper to characterize the claims as merely "mechanism" claims. Inhibition of either urease or Helicobacter pylori (an undesirable bacterial infection) should be considered as useful end results in and of themselves, without necessarily treating or preventing another condition or disorder.

a. Written Description

Concerning the written description requirement, the Office's contention appears to be that inhibiting urease or Helicobacter pylori activity could be related to "as yet unidentified conditions/activities/disorders." (Office Action, pg. 2.) According to the Office, the specification lacks support for any treatment other than ulcer treatment. (*Id.*)

First, it is not correct to say that the present specification only addresses ulcer treatment. Indeed, page 1, lines 9-13 of the specification discloses that urease produced by Helicobacter pylori has a close relationship to the development of

gastrointestinal diseases, of which gastroduodenal ulcer is merely one example. Further, test Example 1 demonstrates activity of compounds of formula (1) against urease from two sources: Helicobacter pylori and jack bean. (Page 22-25.) Test Example 2 additionally addresses anti-Helicobacter pylori activity of compounds of formula (1). (Page 25-27.)

Second, the requirements for written description are more than met in the present case. Specifically, "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." MPEP § 2163 (*Citing Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991)). In the present case, claims 5-8 recite, among other things, methods of inhibiting urease and Helicobacter pylori activity. Based on the tests disclosed in the specification, showing activity against both urease and Helicobacter pylori, there can be no question that the inventors had possession of the claimed invention. *See also MPEP* 2107.02 ("data generated using in vitro assays ... almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process").

Finally, it has never been the case that an application must disclose all possible embodiments of an invention. *AK Steel Corp. v. Sollac*, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003). Indeed, an application does not even need to contain any working examples. MPEP § 2164.02 (citing *Gould v. Quigg*, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987)). Thus, the possibility that inhibiting urease or Helicobacter pylori activity could

relate to "as yet unidentified conditions / activities / disorders" (Office Action, pg. 2) does not support a rejection for lack of written description.

Accordingly, Applicant maintains that it is clear that the inventors had possession of and adequately described methods for inhibiting urease or Helicobacter pylori activity, as claimed. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

b. Enablement

On the issue of enablement, the Office further questions the utility of the claims, and contends that one "would not be able to use the inventive compound as claimed without undue experimentation." (Office Action, pg. 3.) However, the Office's position in this regard is contrary to well-settled principles of U.S. patent law.

First, concerning the issue of utility, adequate proof of any pharmacological activity constitutes a showing of practical utility. *Nelson v. Bowler and Crossley*, 206 USPQ 881 (CCPA 1980). Moreover, so long as an asserted utility is credible, a rejection based on "lack of utility" is not appropriate. MPEP § 2107.01. In addition, as in *In re Brana*, the absence of disclosure of a specific disease against which the claimed compounds are useful is not the basis for a rejection on the grounds of undue experimentation. 34 USPQ2d 1436, 1439-40 (Fed. Cir. 1995). In the present case, the specification has multiple examples of pharmacological activity. The Examiner has also not identified any basis to question the credibility of this evidence of utility.

Second, on the issue of enablement more directly, the Federal Circuit has explained that while the specification must enable full scope of the claimed invention "[t]hat is not to say that the specification itself must necessarily describe how to make

and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp. v. Sollac*, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003) (citations omitted). In the present case, the Office does not question that Applicant has enabled urease and Helicobacter pylori inhibition. Rather, the Office appears to argue that not all possible diseases or conditions that could stem from urease or Helicobacter pylori are addressed in the specification. However, the fact remains that the claimed inhibition is indisputably enabled. The possibility that inhibiting urease or Helicobacter pylori activity could relate to "as yet unidentified conditions / activities / disorders" (Office Action, pg. 3) is, therefore, of no consequence.

Accordingly, Applicant maintains the claimed urease and Helicobacter pylori inhibition have sufficient utility and are enabled without undue experimentation. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

IV. REJECTIONS UNDER 35 U.S.C. § 102

Claims 5-8 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by JP 04077476 to Hirai ("Hirai"). (Office Action, pg. 3.) The Office contends the 1,2-benzoisothiazol-3-(2H)-one according to Hirai would inherently inhibit urease and act as an anti-Helicobacter pylori agent "since it is well known in the art that Helicobacter pylori is the culprit of peptic ulcer disease." (Office Action, pg. 3.) The Examiner further maintains that "the method of treating ulcer in a patient [according to Hirai] using the same prior art compound would inherently inhibit urease activity and a Helicobacter pylori activity, since Helicobacter pylori is commonly known to be the

cause of ulcer." (*Id.*) The Office then cites page 28, lines 3-6 in support of this contention. (*Id.*) Applicant respectfully disagrees and traverses the rejection.

Legally, to establish inherency, as the Office has attempted to do in this case, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference ...." Continental Can Co. USA, Inc. v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis added). It is also well settled that "[i]nherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. (internal citations omitted) (emphasis added). That is, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Moreover, the burden of establishing inherency clearly rests on the Office. See, for example, Ex parte Levy, 17 USPQ2d 1461, 1463-64 (BdPatApp&Int 1990) (Reversing a rejection based on inherency because the Examiner failed to meet "the initial burden of establishing a prima facie basis to deny patentability to a claimed invention [which] rests upon the examiner.")

The central premise in the present rejection is that the treatment of an ucler according to Hirai would "inherently inhibit urease activity and a Helicobacter pylori activity." (Office Action, pg. 3.) However, this premise is not factually supported. In particular, not all ulcers are caused by Helicobacter pylori. For example, ulcers may be caused by use of nonsteroidal anti-inflammatories ("NSAID") drugs, such as aspirin and ibuprofen, as well as other diseases. See, e.g., "Reduce Your Risk," brochure from the American Gastroenterological Association and American Pharmacists Association

(Attachment 1). Ulcers can thus occur in the absence of any Helicobacter pylori infection. Therefore, treatment of an ulcer is not necessarily treatment of a Helicobacter pylori associated ulcer. Accordingly, even if Hirai does teach treating ulcers with a compound within the scope of the present claims, because not all ulcers would necessarily be associated with urease or Helicobacter pylori Hirai does not inherently teach inhibiting urease or Helicobacter pylori activity.

Additionally, many common ulcer treatments are not directed to inhibition of urease or Helicobacter pylori activity. For example, the drug omeprazole (cited for comparison in the Hirai abstract) is known as a "proton-pump" inhibitor due to its H^+, K^+ -ATPase activity, which decreases the amount of acid produced in the stomach. (See entry for "Prilosec®", in Physicians' Desk Reference ("PDR"), pages 633-638, at 637 (2004) (copy enclosed as Attachment 2).) Ulcers and other gastric conditions treated by omeprazole may be caused by conditions other than Helicobacter pylori infection, and omeprazole thus does not necessarily or directly inhibit urease or Helicobacter pylori activity. (See PDR at 636 (Prilosec® indicated treatment, among other things, active duodenal ulcer, distinct from treatment of duodenal ulcers associated with *H. pylori* infection, and active benign gastric ulcer, without suggestion of associated discussion of *H. Pylori* infection.) Accordingly, the disclosure of a compound to treat ulcers (*e.g.,* omeprazole or a compound according to formula (1)) is not necessarily the same as the use of that compound to inhibit urease or Helicobacter pylori activity. Indeed, according to the PDR, an antibiotic must be used with omeprazole to treat Helicobacter pylori infections associated with ulcers. (*E.g.,* PDR at 636.)

In fact, Hirai only suggests that their compounds have H^+, K^+ -ATPase proton-pump activity. (Hirai, Abstract.) Since proton-pump inhibitors are indicated for the treatment of ulcers not necessarily associated with Helicobacter pylori, the use of a compound according to Hirai to treat ulcers would not necessarily (as required for a rejection based on inherency) inhibit urease or Helicobacter pylori. This is true regardless of whether the compound also has anti- urease or Helicobacter pylori activity.

The portion of the specification at page 28, lines 3-6 cited by the Office (Office Action, pg. 3) also does not support the Office's contention that use of a compound to treat an ulcer would inherently inhibit urease or Helicobacter pylori activity. Specifically, the statement in the specification is that "[t]he drugs of the present invention are effective to prevent and treat gastrointestinal diseases caused by urease of Helicobacter pylori, such as chronic gastritis and gastroduodenal ulcer." (Page 28, lines 3-6 (emphasis added).) However, while urease of Helicobacter pylori may cause some ulcers, this statement does not say that all ulcers are caused by urease of Helicobacter pylori.

The Office has thus failed to distinguish between inherent properties of a compound, which are not in dispute, and the necessary and inherent result of treating ulcers according to Hirai. Because Hirai is not cited for teaching the use of compounds according to formula (1) for the sub-class of ulcers caused by or associated with urease or Helicobacter pylori, a teaching of ulcer treatment according to Hirai does not inherently teach inhibition of urease or Helicobacter pylori.

Moreover, because Hirai is not cited for recognizing any anti- urease or Helicobacter pylori activity, there is also no suggestion to use a compound according to formula (1) to inhibit urease of Helicobacter pylori activity. Accordingly, the pending and proposed claims would also not have been obvious over Hirai.

For at least the above reasons, reconsideration and withdrawal of the rejection are respectfully requested.

V. CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 14, 2004

By: _____
Mark J. Feldstein
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Attachments:

1 "Reduce Your Risk," brochure from the American Gastroenterological Association and American Pharmacists Association (as download from http://www.2reduce.org/docs/REDUCE_Brochure_Final.pdf on October 4, 2004).

2 Entry for "Prilosec®", in Physicians' Desk Reference, pages 633-638 (2004).